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Standard Setting Principles

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16. ABSTRACT

The basis for setting drinking water standards has not changed much in principle during the past decade, but the procedure for creating them in an open manner has caused the United States, at least, to go through a much more elaborate process to obtain approval and support from the public.

The Safe Drinking Water Act of 1974 specifies the type of contaminants that must be regulated, that is, those that may have an adverse health effect. Additionally, if a proposed maximum contaminant limit cannot be sensibly determined and monitored then a treatment technique regulation may be used to help the States and utilities cope with the problem. With these conditions as a legislative or legal framework upon which to build, much information about occurrence, monitoring potential, health effects, and treatment costs must be gathered before a new standard is proposed.

This presentation will briefly cover the steps (with examples) that the U.S. EPA must go through to create proposed regulations (standards) for the volatile organic compounds found in some ground waters.

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STANDARD SETTING PRINCIPLES

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Historically the United States government for many decades has tried to protect the health of the Public that drink water from Interstate Carriers by setting a bacterial standard for coliform. This standard, or limit, was established to help prevent the spread of waterborne diseases. State Health Departments usually followed the lead set by the U.S. Public Health Service (USPHS) and adopted the same standard for use in their State.

Later on, in 1946 and 1962, the USPHS made recommendations to limit certain chemicals in potable water. These too the States adopted. The principle applied in all cases was to protect the health of the people in both the short and the long run, and also to make sure the drinking water was esthetically acceptable.

In 1974, the Safe Drinking Water Act was passed by the U. S. Congress and it mandated that National Drinking Water Regulations be written, but they expected the State Governments to adopt and implement the Standards. This Act caused the U. S. Environmental Protection Agency (EPA) to initiate a procedure for preparing regulations that is much more elaborate and open than the previous procedure.

Within a few months after passage of the Act, EPA had to issue interim regulations based on the best information available. This was done by using the 1962 USPHS Standards, plus a few others, such as for mercury and pesticides. These were issued to "protect health to the extent feasible," using generally available technology and taking cost and other factors into consideration.

The next step was to have the National Academy of Sciences (NAS) conduct a review to access the potential health effects of contaminants in drinking water which might be harmful and to provide EPA with proposed Recommended Maximum Contaminant Levels (RMCLs). These levels were to be set where "no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin for safety." These then are health goals, but not necessarily enforceable standards.

Following the establishing of these RMCLs, EPA is expected to set MCLs as close to the RMCLs as is feasible, and this would reflect allowance for the cost and feasibility of treatment. NAS did issue a report, but it did not contain any specific RMCLs, so EPA decided to issue an Advance Notice for Proposed Rule Making (ANPRM) in the Federal Register so as to invite the public to comment on various standards the Agency proposed to revise or add.

In the case of Volatile Organic Contaminants (VOCs) frequently found in some ground waters, an ANPRM was issued in the Federal Register on March 4, 1982. It stated: "EPA is considering a

wide variety of alternatives, ranging from non-federal regulatory approaches, such as the provision on information and guidance to the establishment of formal, enforceable standards."

To enhance this review process, EPA had the AWWA Research Foundation conduct four public workshops pertaining to source, monitoring, health, treatment and costs. A public hearing also was conducted by EPA.

Some of the concerns and principles considered during these sessions were as follows: Monitoring for VOCs

1. Are the analytical methods suitably accurate for the measurement of these contaminants at expected concentrations?

2. Can they be improved or made less expensive?

3. Are a sufficient number of qualified laboratories available?

4. What level of precision and accuracy performance can be expected from these laboratories?

5. What are the commercial laboratory costs for analyses for volatile organics?

Human Health Considerations

The human health considerations involving possible hazardous chemicals relied heavily on the four principles stated by the NAS. These included:

1. Effects in animals are applicable to man properly qualified.

2. Methods do not now exist to establish a threshold for longterm effects of toxic agents.

3. Exposure of experimental animals to toxic agents in high doses is a necessary and valid method of discovering possible carcinogenic hazards in man.

4. Material should be assessed in terms of human risk, rather than as "safe" or "unsafe."

In the case where chemicals are found to be carcinogenic, risk models are used to calculate concentrations which, if consumed over a lifetime at a rate of two liters per day, might result in excess life time cancer risks of 1/10,000, 1/100,000 and 1/1,000,000. The range of projected upper limit risks for cancer can be used as a guide to understanding the potential for excess cancer risks that will result from consumption of drinking water that contains VOCs, at various concentrations. Care should be taken not to over emphasize their accuracy or precision, however, and in some cases non-carcinogenic health risks may be equally significant.

Assessing the risk is done by determining through animal toxicological experiments and/or human epidemiological studies that a compound is a carcinogen, determining the extent to which a population is exposed, and then estimating the probability of a particular disease that will occur in the population.

Risks in human populations at the usual environmental exposure levels are generally unmeasurable by epidemiological studies; therefore, risk extrapolation from animal tests is generally recognized as the best method for estimating the magnitude of potential human health risks associated with non-threshold toxicants. When evaluating low levels of risk in human populations, on the order of one additional case per 10,000 or 100,000 - levels which normally cannot be measured by epidemiology, experiments involving many thousands of animals are necessary, but they are are very difficult and expensive to conduct. Thus animal tests are usually conducted at dose levels 100 to 1,000 or more times higher than would be expected in drinking water to compensate for the differences in population size.

Treatment and Cost Considerations

The approach taken to fulfill the requirements of the Act regarding treatment feasibility to EPA is to publish a summary of "Generally Available Technology" for a specific MCL. This was done in the settlement of the trihalomethane (THM) legal dispute with the American Water Works Association (AWWA). It allowed all parties to know which treatment processes are realistic for a certain contaminant. For example, in the case of THM, an agreement finally was reached that granular activated carbon contactors were considered impractical for water utilities to use to achieve compliance with the THM standard, but that may not be the case for the VOCs under consideration at this Workshop.

Discussing all these principles and methods in open forums has added considerably to the scientific and technical record, but also has served to inform many utility managers and consumers about the state of our information on health, treatment, and surveillance.

After analyzing all this information, proposals are made for new MCLs. This package must contain extensive documentation regarding health, treatment, costs, benefits, and analytical methods. This may be reviewed by the Administrator's Science Advisory Board and the National Drinking Water Advisory Council before being published in the Federal Register for public comment. After analysis and review of all of the comments obtained both in writing and in public meetings the proposal is revised as necessary by EPA, receives additional technical and policy review within the Agency and ultimately is promulgated as a final regulation.

Incidentally, since February 1981, a regulatory impact analysis is conducted as part of the development process. The analysis is made when the proposed rule may result in:

1. An annual effect on the economy of $100 million or more; or

2. A major increase in costs or prices for consumer, individual industries, Federal, State or local government agencies; or

3. Significant adverse effects on competition, innovation, or on the ability of the US-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The regulatory impact analysis would contain a description of the potential net benefits and costs. Needless to say, projecting future benefits from controlling carcinogens in drinking water is difficult and imprecise.

As you might imagine, although the process is very democratic, all this open review and thorough analysis of data takes a long time. We have now completed the public comment period for the ANPRM on VOCs and reviewed the hundreds of comments that were received, and the results of the 4 major workshops that were conducted. EPA expects, in 1983, to make a determination of which of the chemicals would warrant standards and to prepare appropriate formal proposals. If they pass all reviews and are promulgated, they probably would not go into effect, however, until 1985 or later. This will allow the States and utilities time to monitor and determine if they are in non-compliance and thus need to change their treatment or water source.

I hope this example with VOCs has helped to show you how we in the U.S. use certain principles and procedures to develop and implement drinking water regulations under our Safe Drinking Water Act.